DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-26-12
Baltimore, Maryland 21244-1850

CMCS Informational Bulletin

DATE: July 24, 2014

FROM: Cindy Mann
Director
Center for Medicaid and CHIP Services (CMCS)

SUBJECT: **Clarifying Information for Quarterly Reporting of Medicaid Drug Rebates in the Medicaid Budget and Expenditure System (MBES)**

This informational bulletin is to provide information to states on reporting Medicaid drug rebates on the *Quarterly Medicaid Statement of Expenditures for the Medical Assistance Program* (the CMS-64) in the Medicaid Budget and Expenditure System (MBES). The combination of CMS reviews of state drug rebate reporting, state requests for clarification, HHS Office of Inspector General Audits, and new Medicaid matching rates available through the Affordable Care Act all underscore the need for CMS to issue this clarifying information to states. The following information is designed to ensure that states are able to report drug rebates on the CMS-64 accurately and consistent with federal requirements.

Specifically, we are reiterating the requirement at section 2500.1 of the State Medicaid Manual that all state collections, including drug rebates, must be reported on the CMS-64 at the applicable Federal Medical Assistance Percentage (FMAP) or other matching rate at which related expenditures were originally claimed. Additionally, we are specifying that states unable to tie drug rebate amounts directly to individual drug expenditures may utilize an allocation methodology for determining the appropriate Federal share of drug rebate amounts reported quarterly. This information identifies the parameters that states are required to adhere to when making such determinations.

Additionally, this information addresses how states must report drug rebates associated with the new adult eligibility group described at 42 CFR 435.119. States that adopt the new adult group may be eligible to claim drug expenditures at increased matching rates. Drug rebate amounts associated with these increased matching rates must be reported at the same matching rate as the original associated prescription drug expenditures. We recognize that states are just beginning to report expenditures and collections associated with these increased matching rates, so we expect this information to provide clarity on associated drug rebate reporting requirements.

Background

The Medicaid Drug Rebate Program

The Medicaid Drug Rebate (MDR) program is a program that includes CMS, state Medicaid agencies, and participating drug manufacturers that helps to offset the Federal and state costs of most outpatient prescription drugs dispensed to Medicaid patients. Approximately 600 drug manufacturers currently participate in this program. All fifty states and the District of Columbia cover prescription drugs under the MDR program, which is authorized by section 1927 of the Social Security Act (the Act).

The program requires drug manufacturers to enter into, and have in effect, a National Medicaid Drug Rebate Agreement with the Secretary of the Department of Health and Human Services (HHS) in exchange for state Medicaid coverage of most of the manufacturer's drugs. When a manufacturer markets a new covered outpatient drug, it must also submit to CMS the product and pricing data concerning the drug via the Drug Data Reporting for Medicaid (DDR) system. This ensures that states are aware of the newly marketed drug. Manufacturers are required to report all covered outpatient drugs under their labeler code to the MDR program and are responsible for paying a rebate on those drugs for which payment was made under the Medicaid state plan. These rebates are paid by drug manufacturers on a quarterly basis to states and are shared between the states and the Federal government to offset the overall cost of prescription drugs provided under the Medicaid program. Additional information about the MDR program can be found at http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Medicaid-Drug-Rebate-Program.html

Quarterly Medicaid Statement of Expenditures for the Medical Assistance Program (CMS-64)

The CMS-64 is the accounting statement that the state agency, in accordance with 42 CFR 430.30(c), submits each quarter under Title XIX of the Act. The CMS-64 is a summary of actual expenditures derived from source documents including invoices, payment vouchers, governmental funds transfers, expenditure certifications, cost reports and settlements, and eligibility records. This form shows the disposition of Medicaid grant funds for the quarter being reported and any prior period adjustments. It also accounts for any overpayments, underpayments, refunds received by the state Medicaid agency, and income earned on grant funds. The form is used to reconcile the Medicaid funding advanced to the state for the quarter, made on the basis of the *Medicaid Program Budget Report* (CMS-37), with actual expenditures for the quarter. The state submits this form electronically to CMS 30 days after the end of each quarter via the Medicaid and Children's Health Insurance Program Budget and Expenditure System (MBES/CBES).

The amounts reported on the CMS-64 and its attachments must represent actual expenditures for which all supporting documentation, in readily reviewable form, has been compiled and which is available at the time the claim is filed. CMS must assure that state expenditures claimed for Federal matching under the Medicaid program and associated collections are programmatically reasonable, allowable, and allocable in accordance with existing Federal laws, regulations and policy guidance.

Federal Matching Rates

Section 1903(a) of the Act establishes quarterly payments to states at "…an amount equal to the Federal medical assistance percentage…of the total amount expended during such quarter as medical assistance under the State plan." The FMAP is the rate at which the Federal government matches state medical assistance program (MAP) expenditures. The FMAP rates are determined annually for each state by a formula that is based upon the relationship of the state's average per capita income level to the national per capita income level. The FMAP is limited to a minimum of 50 percent and a maximum of 83 percent.

In addition, higher Federal matching rates for MAP expenditures are applicable to certain expenditures related to Indian Health Facility (100 percent) and family planning (90 percent) services. Children's Health Insurance Program (CHIP) expenditures and optional breast and cervical cancer services also qualify for state-specific higher matching rates. The Affordable Care Act of 2010 established a variety of provider types and services, eligibility groups, and time periods that qualify for increased Federal matching rates. Some state expenditures for individuals in the new adult eligibility group may be eligible for 100 percent FMAP.

CMS-64 Drug Rebate Reporting

All states are responsible for reporting their Medicaid drug expenditures, rebates, and offsets on the CMS-64. States must report Medicaid drug expenditures during the quarter in which the state incurs the expenditure. Any increasing adjustments to the original drug expenditures must be claimed at the FMAP or other matching rate at which the original expenditures were claimed. Additionally, states must report decreasing adjustments to drug expenditures, drug rebates, and drug offsets at the FMAP or matching rate at which the original Medicaid drug expenditure was claimed.

The line items for Medicaid drug expenditures, rebates, and offsets on the CMS-64 include fee-for-service (FFS) and managed care organization (MCO) and are as follows:

- 7 – Prescribed drugs
- 7A1 – Drug rebate offset – National agreement for FFS 7A2 – Drug rebate offset – State sidebar agreement for FFS (same as state supplemental rebate agreement for FFS)
- 7A3 – MCO – National rebate agreement (effective March 23, 2010 under the Affordable Care Act)
- 7A4 – MCO – State sidebar agreement (same as state supplemental rebate agreement, effective March 23, 2010 under the Affordable Care Act)
- 7A5 – Increased ACA offset – Fee for Service – 100% (effective January 1, 2010 under the Affordable Care Act)
- 7A6 – Increased ACA offset – MCO – 100% (effective March 23, 2010 under the Affordable Care Act)

Please note that rebates received under the National Medicaid Drug Rebate Agreement (Lines 7A1 and 7A3) are separate from rebates received under state supplement rebate agreements (Line 7A2 and 7A4). Please do not combine the state supplement rebates with the national rebates when reporting on the CMS-64.

Methods for Determining FMAP for Drug Rebate Amounts

As described in the section 2500.1 of the State Medicaid Manual, we require states to report all state collections and recoveries at the matching rate at which the original expenditure was claimed. When reporting drug expenditure collections and recoveries, including drug rebates on the CMS-64, we require states to employ the most accurate method in determining the correct federal matching rate. The most accurate method for reporting rebate amounts consists of the state identifying each rebate amount and tying it to the matching rate of original related drug expenditure that the state claimed on the CMS-64.

However, we recognize that some states and manufacturers may face various challenges that provide a barrier to reporting drug rebate amounts that tie directly to an individual original drug claim. Therefore, we are also permitting states to submit report drug rebate amounts on the CMS-64 utilizing an allocation methodology to tie aggregate drug rebate amounts each quarter to the varying matching rates at which the original drug expenditures were claimed. This option is only available to states that are currently unable to tie drug rebate amounts directly to individual drug expenditures. States that currently report drug rebate amounts on the CMS-64 by tying the rebate amounts directly to the original expenditures must continue to utilize this method.

Acceptable Allocation Methodologies

Allocation Principles

If a state is unable to tie drug rebate amounts directly to individual drug expenditures, it may elect to utilize an allocation method to identify the different expenditure categories and matching rates at which it must report drug rebate amounts. The allocation method must rely on historical drug expenditure data reported on the CMS-64 as a basis to allocate drug rebate amounts to various matching rates for purposes of reporting on the CMS-64 quarterly.

All state allocation methodologies must adhere to the following parameters:

- The methodology must attempt to allocate rebates as accurately as possible to original expenditures based on the historical distribution of expenditures and drug rebates.
- The methodology must rely on actual drug expenditures reported on the CMS-64.
- The allocation percentage must be calculated on a quarterly basis.
- The allocation data must be based on the prior four quarters' drug expenditure data (unless the use of data from fewer quarters is more accurate).

- The state must maintain adequate supporting documentation regarding its allocation methodology and its quarterly application of the allocation methodology.

- If the expenditure is eligible for FFP at more than one matching rate, the methodology must assign the highest matching rate at which the expenditure was claimed (e.g. – a service eligible at the family planning matching rate that is also eligible at the Indian Health Services matching rate).

- The methodology must not be designed to minimize federal funds reported to CMS.

- The methodology must be consistent across time periods so as not to decrease the amount of federal funds to be returned (e.g. – the state cannot use multiple allocation methodologies selectively after determining which method reports the least amount of FFP associated with drug rebates).

2014 New Adult Group Drug Rebate Amounts

We expect the quarter ending June 30, 2014 will be the first quarter for which states will report significant drug rebate amounts associated with enrollees in the new adult group described in 42 CFR 435.119. For states adopting the new adult group, the state's allocation methodology must account for the limited adult group drug expenditure experience to ensure that drug rebate amounts are reported at the appropriate matching rate. Specifically, these states are required to use drug expenditure data from a shorter time period to ensure that drug rebates associated with the new adult group are not understated.

For example, if a state adopted the new adult group effective January 1, 2014, the state would only have two quarters of drug expenditure data relating to the new adult group when it is required to report rebate amounts on the CMS-64 for the quarter ending June 30, 2014. The parameters above require the use of four quarters of data. However, the allocation methodology would be more accurate if the state only uses data from quarters in which it would have new adult group expenditure data. In this example, the state would only utilize drug expenditures from the first two calendar quarters of 2014 when allocating drug rebate amounts to various matching rates. States should continue to use data from less than four quarters until such time as four quarters of data related to new adult group drug expenditures becomes available.

We look forward to continued efforts and commitment from states in ensuring that drug rebates are reported at the appropriate matching rate on the CMS-64. Should you have any questions please contact Rory Howe, Director of the Division of Financial Operation at 410-786-4878 or by email at rory.howe@cms.hhs.gov.